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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
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EXAMINER

MARSCHER, ARDIN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/915,044 | SAMPSON ET AL. | |
| | Examiner | Art Unit | |
| | Ardin Marschel | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11-13, 21, 57-59, 62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11-13, 21, 57-59, 62 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>12/2/04</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicants' arguments, filed 8/6/04, have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The After final amendment, filed 8/6/04, has been entered. Due to the newly found basis of rejection as summarized below, the finality of the Office action, mailed 6/3/04, is hereby withdrawn.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 11-13, and 21 are rejected under 35 U.S.C. 102(e)(1) as being clearly anticipated by De Lumley-woodyear et al. (PreGrant Publication 2002/0081588).

This reopening of prosecution has been caused by a reconsideration of the disclosures within De Lumley-woodyear et al. and the finding that a herein newly applied basis for rejection of the above listed instant claims is deemed proper which is different from the basis in this reference that has been described in the previous two

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Office actions. This change in rejection basis has necessitated this reopening of prosecution.

Instant claim 1 cites two options of moieties attached to a target probe in part (a). One of these is a bioconjugate pair member which binds to the other member of a bioconjugate pair. The reference cites the attachment of an enzyme to the target probe which enzyme was characterized in the previous office action as a redox moiety. In this rejection such an enzyme is characterized as one member of a bioconjugate pair which is an option as noted above in instant claim 1. This bioconjugate pair member is described in part (a) of instant claim 1 via the phrase "that binds to the other member of a bioconjugate pair...and acceptors" as in lines 8-11 of instant claim 1. This binding phraseology is reasonably interpreted as a characteristic of such a bioconjugate pair member which is also a characteristic of an enzyme of the reference. Paragraph [0111] of the reference goes on to disclose that the enzyme catalyst described therein is present in a sequence of reactions which results in electrooxidation or electroreduction of the substrate of the enzyme. In paragraph [0114] the enzyme is described as being glucose oxidase which is electrooxidizes glucose after hybridization. Glucose is therefore a redox active moiety as set forth as bound by the bioconjugate member as a specie of such a redox active moiety in instant claim 1, part (a), last 4 lines. Other citations within the reference support this rejection as summarized below as well as the rejection of certain additional instant claims.

De Lumley-woodyear et al. is a publication directed at electrochemical detection of nucleic acid sequences as summarized in the abstract. In particular Figures 10, 15A,

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and 15C depict an electrode assembly wherein a redox moiety (polymer) is situated on a electrode to which sample target nucleic acid is hybridized to probe oligonucleotides in what is reasonably interpreted as a detection cell as utilized in the instant claims.

The device is described in paragraph 0010 as an array of individual microelectrodes which are individually addressable. A significant instant claim 1 limitation is the activation of the redox moiety via electrode stimulus via addressable stimuli to each electrode. The individual addressable stimuli activation of electrodes, as in instant claim 1, part (b) and (b), subpart (i), is described in paragraphs 0010 and 0011. The remainder of instant claim 1 is directed to relatively well known electrode based detection methodology. This electrode based detection methodology is, however, also disclosed in the reference in the sample (with target) depiction in Figure 15C and paragraphs 0042 and 0043 wherein hybridization of the target results in an electrical signal response "if" a target hybridizes to a sensor oligonucleotide as in the last 4 lines of instant claim 1. A general summary of the method of the reference; which also anticipates the overall methodology of the instant claims 1, 2, 12, and 13; is set forth in the reference in paragraphs 0110 – 0111.

The stimulus application via off substrate circuitry in analog values as required for instant claim 4 is set forth in paragraphs 0122 – 0125 in a detailed description of this practice. The individual addressing of such stimuli to each cell is described in the reference in paragraph 0129 as well as the individual addressability in paragraph 0010 which is interpreted as a digital addressability, as in instant claim 3, considering also the large number of sensor cells disclosed in paragraph 0034 ranging from 4 to 10,000.

Several of the Figures, such as Figure 5, shows the voltammetry detection in the reference as cited in instant claim 21.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 11-13, 21, 57-59, 62, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn et al. (P/N 6,686,150).

In the abstract the reference summarizes the invention as being directed to signal amplification utilized in nucleic acid detection through the use of an electron transfer moiety (ETM). A variety of hybridization format for this practice is depicted in Figures 14-19B and 27A – 35B. The disclosure, in particular, of sandwich hybridization formats is set forth in column 4, lines 43-55, which describes a probe/target complex which if formed attached to an electrode followed by label probe with ETM thereon hybridization to said complex. Probes utilized therein include oligonucleotides of various length as described in column 14, line 62, through column 15, line 47, wherein short probes of 10 – 50 nucleotides are described in column 15, lines 35-41, which

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qualify as oligonucleotide probes as also cited in instant claim 57, part (a). Said probe/target complex is the type as formed on test sites in instant claim 57, part (a). The label probe/ETM hybridization to said probe/target complex extends and incorporates the ETM thereby to result in electrical detection via current flow (electron transfer as in column 4, lines 50-55) via said electrode. Said extension thus anticipates the limitations of instant claim 57, part (b). The above described ETMs are electronically responsive detector agents as in instant claim 57, part (b), as they respond to electrical signals applied to the electrode for detection. In column 41, line 41, through column 45, line 5, various ETMs are described including transition metal complexes as also instantly cited in the claims. An array format for the above detection practice is described in column 58, line 46, through column 59, line 28, wherein the independent addressability of the electrodes is cited on biochips in column 58, lines 17-28, as cited also in instant claim 57, part (c). The actual detection via applying a potential to electrodes in the practice of the reference's invention is set forth in column 92, lines 4-13, et seq. The detection of target complex formation via electronic property changes of test sites is set forth in column 96, lines 19-35, as also limitations of instant claim 57, part (d). The probes are nucleic acids as set forth in column 15, lines 59-62, with such nucleic acids being inclusive of RNA or DNA type probes via the nucleic acids definition in column 17, lines 1-18, as also limitations in instant claim 58. Voltammetry etc. detection practices as in instant claim 59 are disclosed as options in column 90, lines 37-50, of the reference. The above cited transition metal complex ETMs are also cited in the instant claims 1 etc. as redox active moiety options thus supporting the

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rejection of instant claims 1 etc. also. Covalent attachment of ETMs to 3' or 5' termini nucleotides of probes is cited in the reference in column 48, lines 42-45, as also limitations of instant claims 62 and 63.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to utilize a number of optional probes, ETMs, hybridization formats etc. from Blackburn et al. to result in the practice of the instant invention. It is noted that a generic optional listing of embodiments as in Blackburn et al. are motivated and suggested via their clear description of such options as in the reference to result in the particular species of the instant claims listed above.

No claims are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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December 2, 2004

J. W. D. W. W. W.
/ JOHN H. LAUSCHEL
EXAMINER
12/7/04